



DES in the Real World

Association Franco-Libanaise 2005

Dr. Joseph Elias





The Changing Face of Interventional Cardiology

- Emphasize evolution from BENESTENT to DES Landmark trials
- Emphasize high relevance of clinical efficacy and safety evidence in complex lesions/patients at high risk for restenosis
- Highlight DES as the broadest and most consistent evidence in treating TODAY'S challenging PCI population





The Changing Face of Interventional Cardiology

The early days of stenting – Stress/Benestent (1994)

Diabetes	16%
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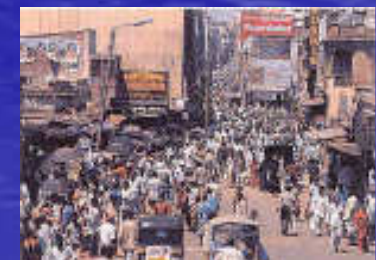
Lesion length (mm)	7-10
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No. of lesions treated	1
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Only de novo lesions

No

- | | | |
|------------|---------------|----------|
| ▪ Acute MI | ▪ Multivessel | ▪ ISR |
| ▪ CTO | ▪ Left main | ▪ Ostial |
| ▪ SVG | ▪ Bifurcation | |





Complexity - Risk Relationship From Concept to Clinical Evidence

- The more complex the lesion / higher the risk for restenosis, the more relevant **ARE** the differences in performance of different stents –
 - BMS vs. DES and CYPHER vs. TAXUS !!
- **Differences include**
 - Late loss
 - Restenosis
 - MACE





DES Players

Major Players

□ Cypher (FDA)

(Rapamycin)

□ Taxus (FDA)

(Paclitaxel)

Minor Players

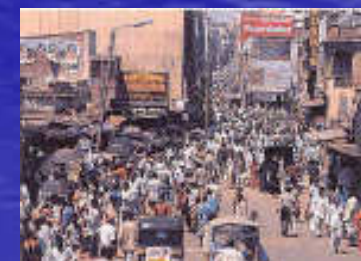
Company	Product	Drug
Medtronic	Endeavor	ABT -578
Sorin	Janus DES	Tacrolimus
Abbott	Dexamet	Dexamethasone
Abbott	Zomaxx	ABT -578
Eucatech	Euca Tax	Paclitaxel
Sahajanand	Infinium	Paclitaxel
Yukon	Yukon	Rapamycin or Paclitaxel
Conor	Constar	Paclitaxel
Biosensors	Biomatrix DES	Biolimus A9
EuroCor	Taxcor	Paclitaxel
Aachen Resonance	Artax	Paclitaxel
AMG	Pico Elite	Paclitaxel





European and US Pivotal Trials: J&J

	RAVEL Trial n=238	SIRIUS Trial n=1058
TLR	2.5% (2 yrs.)	4.1% (9mos.)
MACE, Overall	10% (2 yrs.)	7.1% (9 mos.)
Stent Thrombosis	0% (2 yrs.)	0.4% (9 mos.)
Late Loss	-0.01mm In-stent (6 mos.)	0.17mm In-stent 0.24 mm In-lesion (8 mos.)
Binary Restenosis	0.0% In-stent (6 mos.)	3.2% In-stent 8.9% In-segment (8 mos)





European and US Pivotal Trials: BSC

TAXUS II-SR Trial n=267

TAXUS IV Trial n=1326

TLR

4.7%
(12 mos.)

3.0%
(9 mos.)

MACE, Overall

10.9%
(12 mos.)

8.5%
(9 mos.)

Stent Thrombosis

1.5%
(12 mos.)

0.6%
(9 mos.)

Late Loss

0.31 mm In-stent
0.43 mm Analysis Segment
(6 mos.)

0.39 mm In-stent
0.23 mm Analysis Segment
(9 mos.)

Binary Restenosis

2.3% In-stent
5.5% Analysis Segment
(6 mos.)

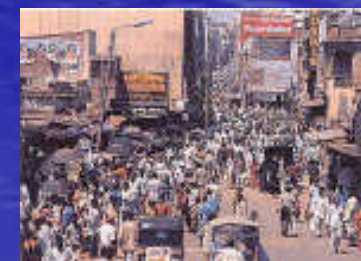
5.5% In-stent
7.9% Analysis Segment
(9 mos.)





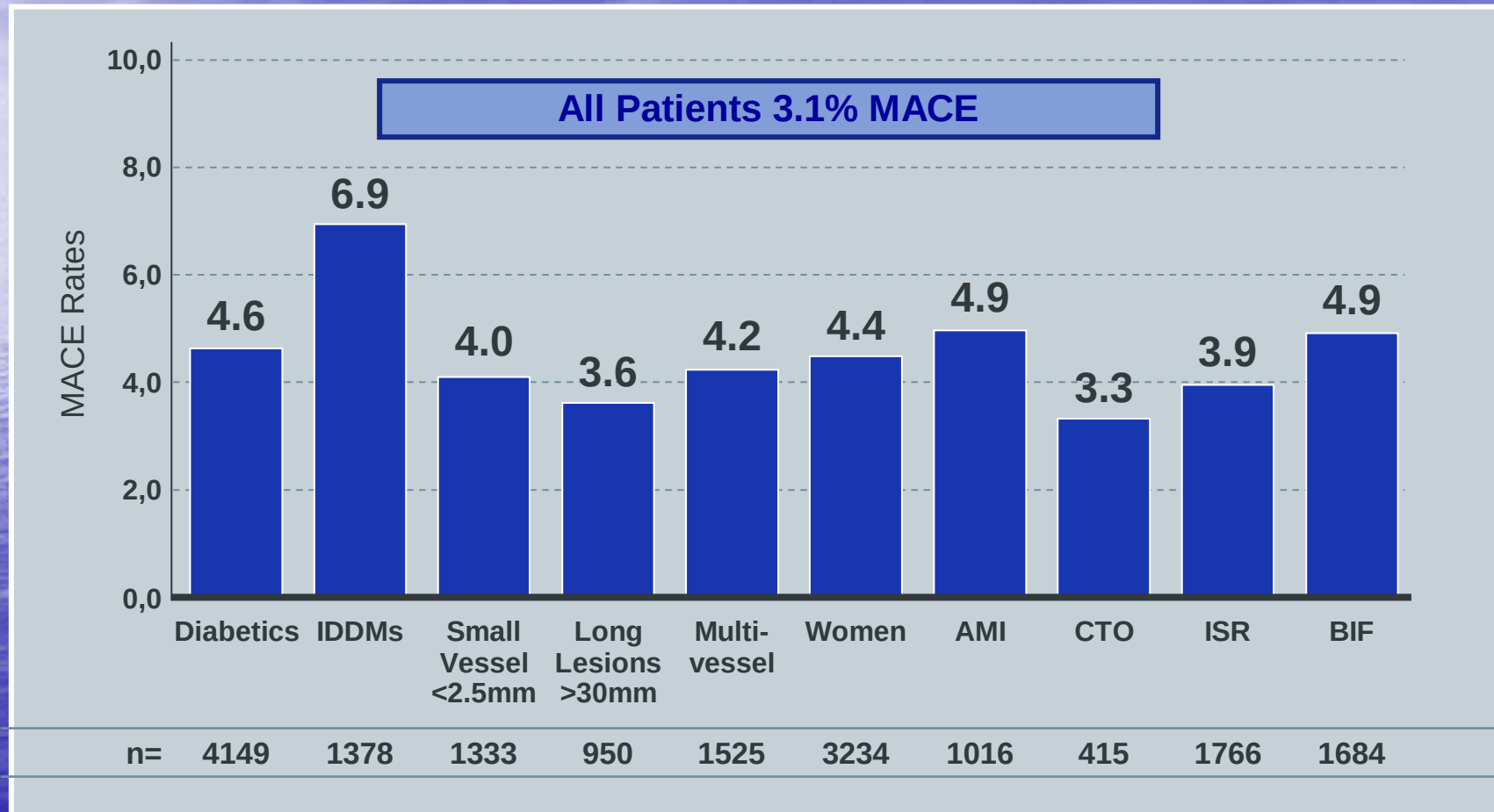
Head To Head Trials

	REALITY (8m)¹ CYPHER TAXUS		SIRTAX (9m)² CYPHER TAXUS	
Late Loss (mm) <i>In Stent</i>	0.09	0.31	0.37	0.49
Late Loss (mm) <i>In Segment</i>	0.04	0.16	0.19	0.32
Binary Restenosis <i>In Stent (%)</i>	7.0	8.3*	3.2	7.6
Binary Restenosis <i>In Segment (%)</i>	9.6	11.1*	6.7	11.9
TLR (%)	5.0	5.4*	4.8	8.3
MACE (%)	9.2	10.6*	6.2	10.8
TVF (%)	10.4	11.5	7.0	11.6
Stent Thrombosis (%)	0.4	1.8	2.0	1.6*
Device Delivery Success (%)	95.3	96.6*	99.0	98.6*





MACE Rates in 'Real World' Patients



MACE at 6 months



DES in the Real World



DES in the
Real World





DES Launch

- Cypher Launch

- Worldwide: April 15, 2002
in Milan By Dr. Antonio
Colombo
- Middle East:
May 15, 2002 in the
American University
Hospital Beirut.
Dr. Alam

- Taxus Launch

- Worldwide:
- Middle East:
March 2003, Al Khalidy
Hospital, Jordan,
Dr. Goussous





DES Penetration Rate % in ME

Country	Q104	Q204	Q304	Q404	Q105	Q205





DES Penetration Rate % in ME

Country	Q104	Q204	Q304	Q404	Q105	Q205
Saudi Arabia	40	50	55	60	55	70





DES Penetration Rate % in ME

Country	Q104	Q204	Q304	Q404	Q105	Q205
Saudi Arabia	40	50	55	60	55	70
United Arab Emirates	40	45	50	55	60	60





DES Penetration Rate % in ME

Country	Q104	Q204	Q304	Q404	Q105	Q205
Saudi Arabia	40	50	55	60	55	70
United Arab Emirates	40	45	50	55	60	60
Pakistan	30	35	35	40	40	45





DES Penetration Rate % in ME

Country	Q104	Q204	Q304	Q404	Q105	Q205
Saudi Arabia	40	50	55	60	55	70
United Arab Emirates	40	45	50	55	60	60
Pakistan	30	35	35	40	40	45
Jordan	10	14	16	20	22	25





DES Penetration Rate % in ME

Country	Q104	Q204	Q304	Q404	Q105	Q205
Saudi Arabia	40	50	55	60	55	70
United Arab Emirates	40	45	50	55	60	60
Pakistan	30	35	35	40	40	45
Jordan	10	14	16	20	22	25
Iran	16	18	20	22	22	24





DES Penetration Rate % in ME

Country	Q104	Q204	Q304	Q404	Q105	Q205
Saudi Arabia	40	50	55	60	55	70
United Arab Emirates	40	45	50	55	60	60
Pakistan	30	35	35	40	40	45
Jordan	10	14	16	20	22	25
Iran	16	18	20	22	22	24
Lebanon	10	11	13	15	18	20





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Country	Q104	Q204	Q304	Q404	Q105	Q205
Saudi Arabia	40	50	55	60	55	70
United Arab Emirates	40	45	50	55	60	60
Pakistan	30	35	35	40	40	45
Jordan	10	14	16	20	22	25
Iran	16	18	20	22	22	24
Lebanon	10	11	13	15	18	20
Egypt	10	11	13	14	15	17





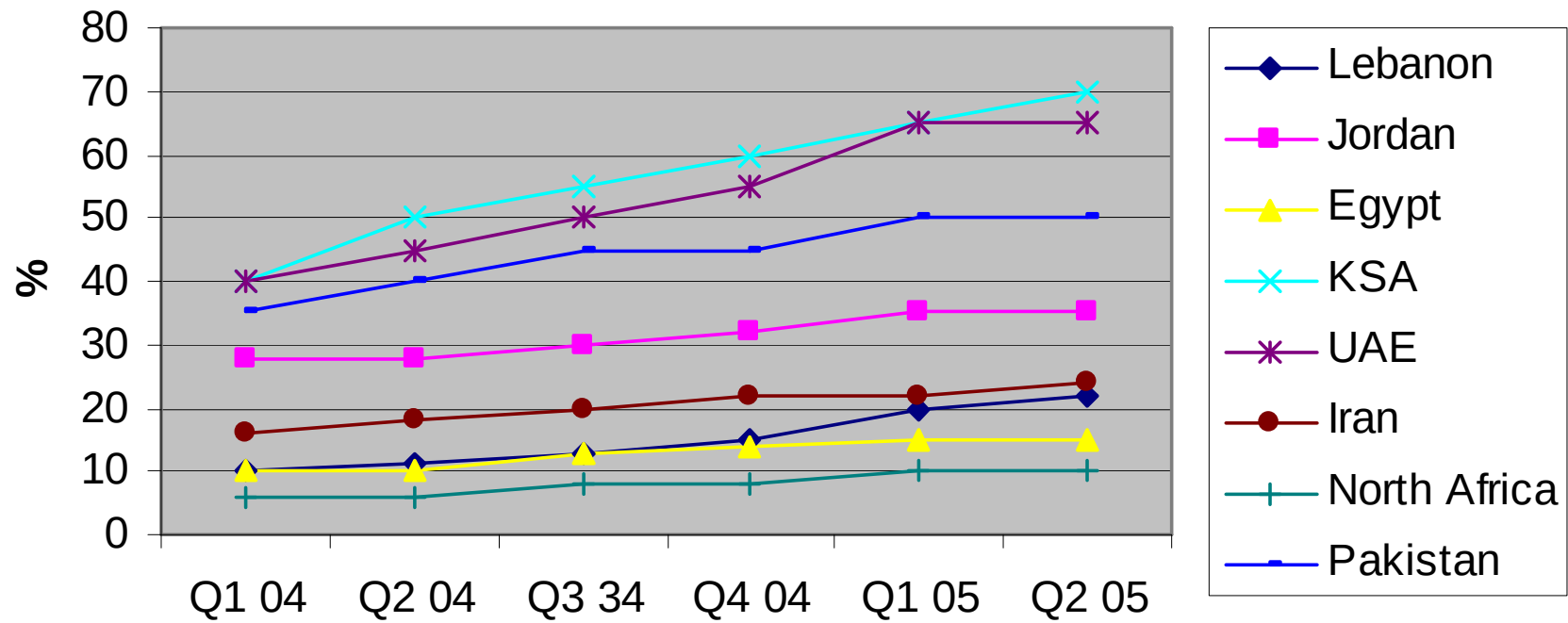
DES Penetration Rate % in ME

Country	Q104	Q204	Q304	Q404	Q105	Q205
Saudi Arabia	40	50	55	60	55	70
United Arab Emirates	40	45	50	55	60	60
Pakistan	30	35	35	40	40	45
Jordan	10	14	16	20	22	25
Iran	16	18	20	22	22	24
Lebanon	10	11	13	15	18	20
Egypt	10	11	13	14	15	17
North Africa	6	6	8	8	10	10



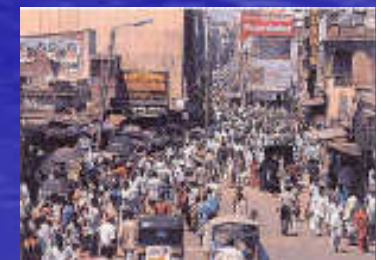
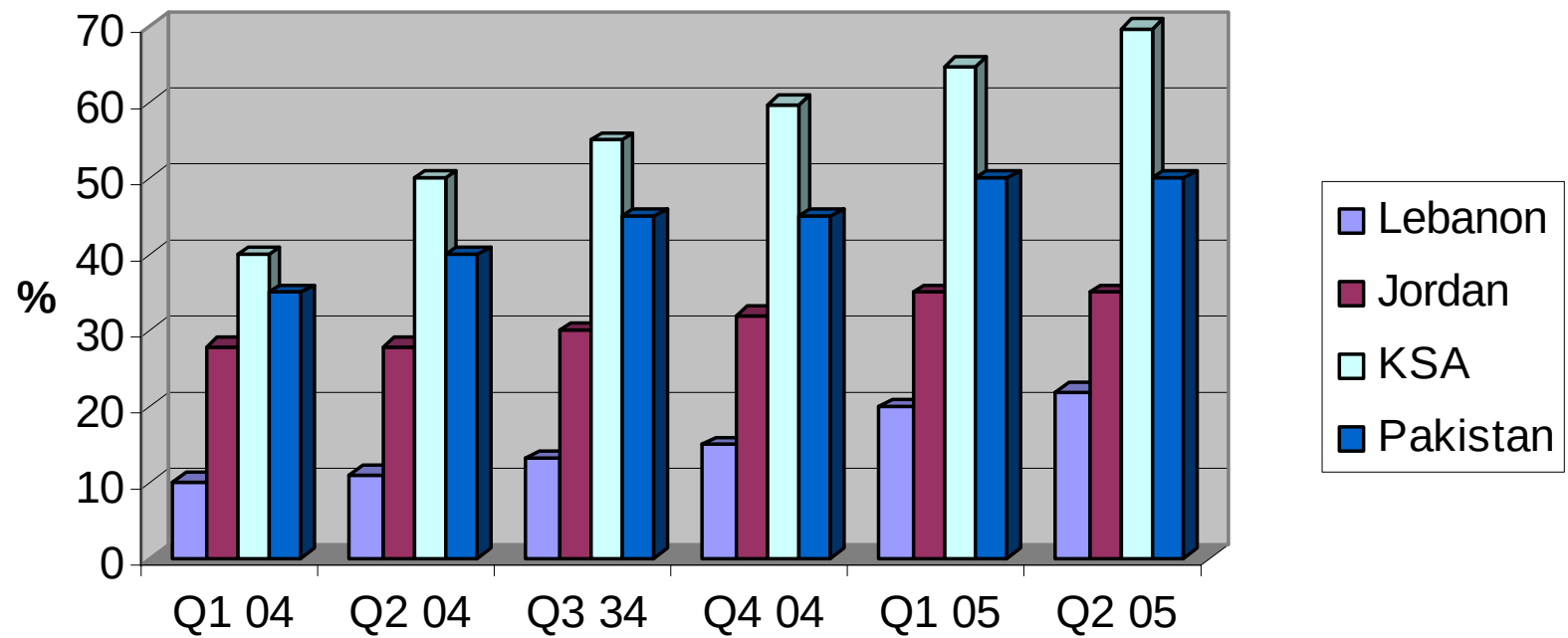


DES Penetration Rate



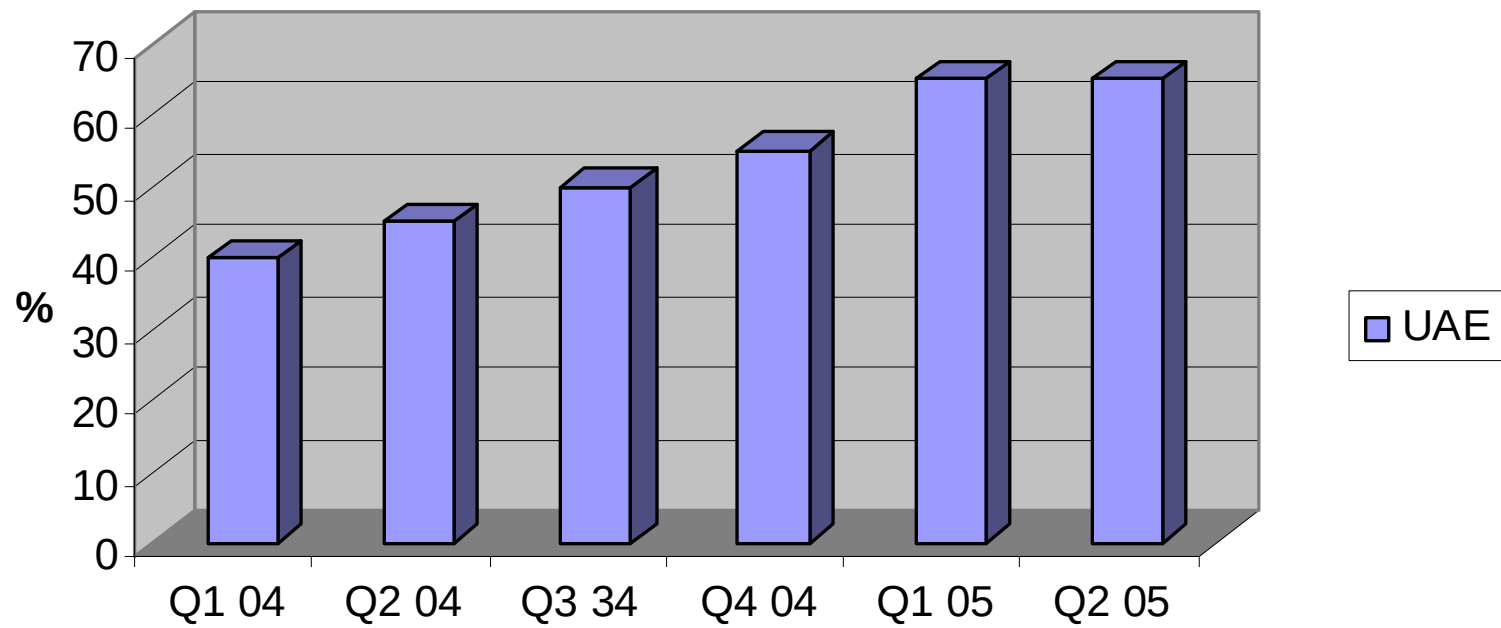


DES Penetration Rate - Upper Gulf



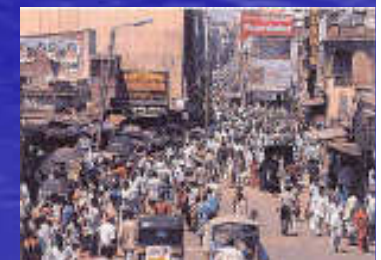
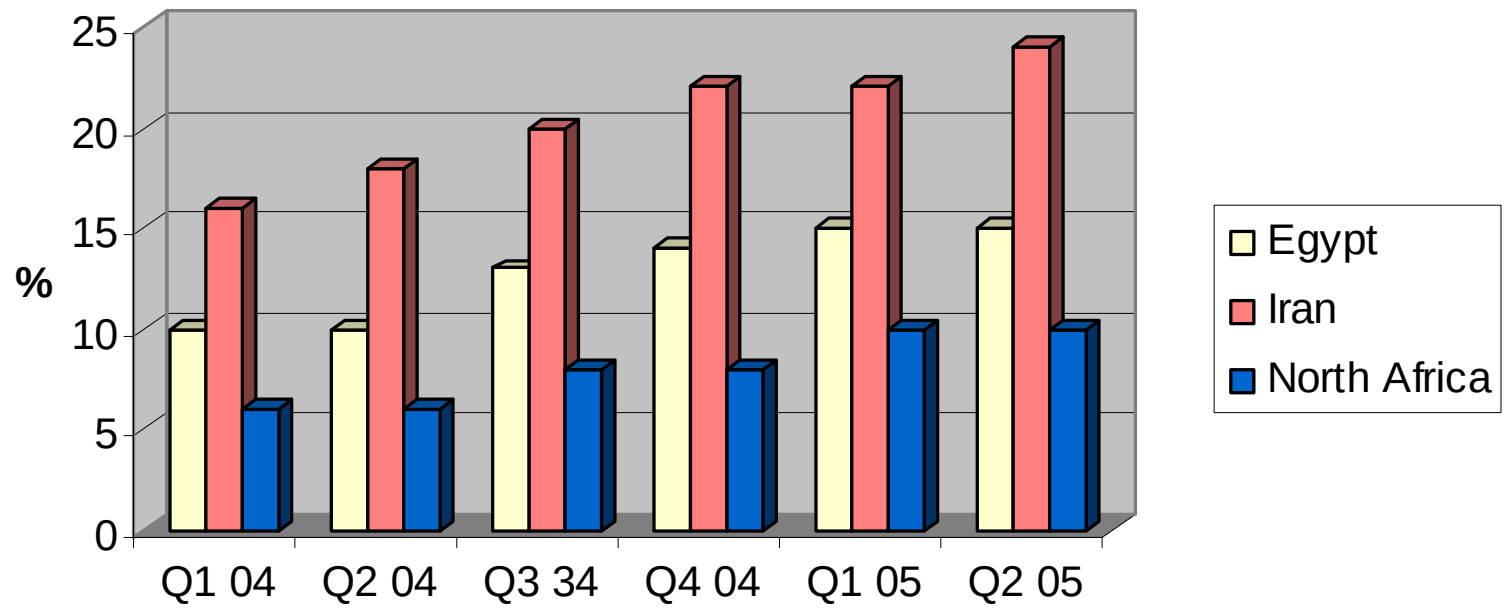


DES Penetration Rate- Lower Gulf





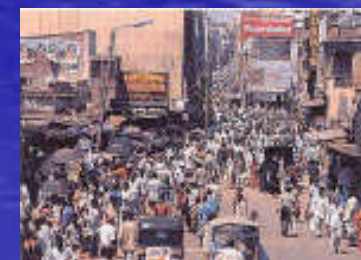
DES Penetration Rate - North Africa





DES Penetration in Europe

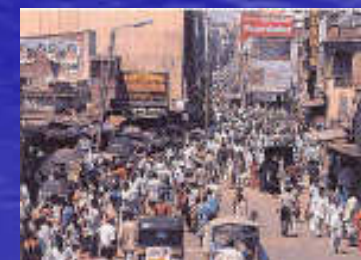
EUROPE		Cordis		Boston Scientific		Other		Total Market	
		Units	MS %	Units	MS %	Units	MS %	Units	%
DES	Q2 CY04	28,098	40%	42,897	60%			70,995	30%
	Q3 CY04	30,820	42%	43,117	58%			73,937	33%
	Q4 CY04	36,825	36%	63,838	63%	1,291	1%	101,954	40%
	Q1 CY05	42,514	40%	61,458	58%	1,591	2%	105,563	42%





SWITZERLAND

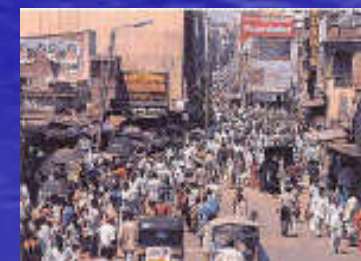
Switzerland		Cordis		Boston Scientific		Other		Total Market	
		Units	MS %	Units	MS %	Units	MS %	Units	%
DES	Q2 CY04	1,669	46%	1,986	54%			3,655	67%
	Q3 CY04	1,480	44%	1,876	56%			3,356	69%
	Q4 CY04	2,052	44%	2,411	52%	168	4%	4,631	77%
	Q1 CY05	2,419	54%	1,896	42%	181	4%	4,496	80%





PORTUGAL

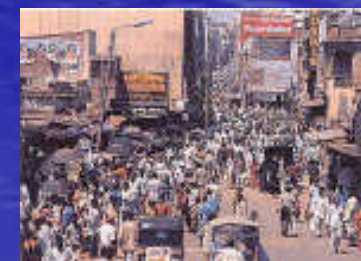
Portugal		Cordis		Boston Scientific		Other		Total Market	
		Units	MS %	Units	MS %	Units	MS %	Units	%
DES	Q2 CY04	1,409	59%	982	41%			2,391	64%
	Q3 CY04	1,283	63%	747	37%			2,030	61%
	Q4 CY04	1,362	50%	1,279	47%	76	3%	2,717	65%
	Q1 CY05	1,463	53%	1,216	44%	73	3%	2,752	79%





AUSTRIA

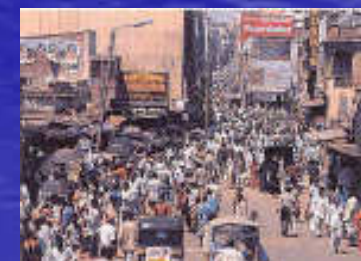
Austria		Cordis		Boston Scientific		Other		Total Market	
		Units	MS %	Units	MS %	Units	MS %	Units	%
DES	Q2 CY04	844	45%	1,017	55%			1,861	42%
	Q3 CY04	748	41%	1,060	59%			1,808	45%
	Q4 CY04	881	35%	1,576	63%	45	2%	2,502	56%
	Q1 CY05	997	39%	1,531	60%	43	2%	2,572	59%





UK & IRELAND

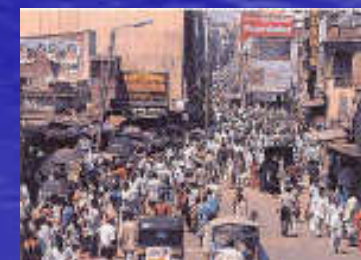
Uk&Ireland		Cordis		Boston Scientific		Other		Total Market	
		Units	MS %	Units	MS %	Units	MS %	Units	%
DES	Q2 CY04	2,751	21%	10,441	79%			13,192	45%
	Q3 CY04	4,376	28%	11,188	72%			15,564	50%
	Q4 CY04	4,582	22%	16,430	78%	97		21,109	60%
	Q1 CY05	5,048	30%	11,492	69%	92	1%	16,632	55%





NORDIC

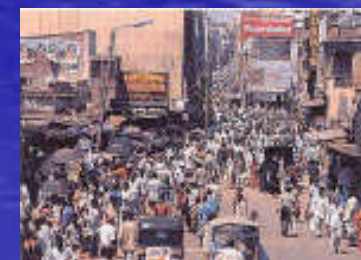
Nordic		Cordis		Boston Scientific		Other		Total Market	
		Units	MS %	Units	MS %	Units	MS %	Units	%
DES	Q2 CY04	1,774	33%	3,534	67%			5,308	39%
	Q3 CY04	1,899	32%	3,993	68%			5,892	43%
	Q4 CY04	2,782	35%	5,097	65%			7,879	51%
	Q1 CY05	3,745	46%	4,388	54%	17		8,151	54%





SPAIN

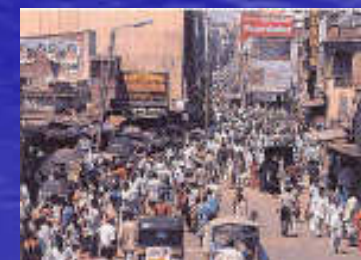
Spain		Cordis		Boston Scientific		Other		Total Market	
		Units	MS %	Units	MS %	Units	MS %	Units	%
DES	Q2 CY04	1,097	21%	4,012	79%			5,109	37%
	Q3 CY04	1,993	38%	3,268	62%			5,261	40%
	Q4 CY04	1,915	27%	4,779	68%	338	5%	7,032	48%
	Q1 CY05	2,386	30%	5,245	66%	334	4%	7,965	52%





FRANCE

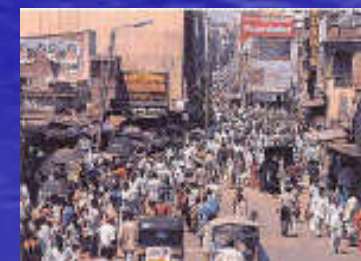
France		Cordis		Boston Scientific		Other		Total Market	
		Units	MS %	Units	MS %	Units	MS %	Units	%
DES	Q2 CY04	6,641	47%	7,423	53%			14,064	35%
	Q3 CY04	6,835	51%	6,655	49%			13,490	39%
	Q4 CY04	7,617	40%	11,258	59%	165	1%	19,040	45%
	Q1 CY05	9,114	42%	12,231	57%	234	1%	21,580	50%





ITALY

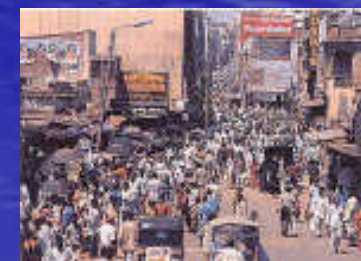
Italy		Cordis		Boston Scientific		Other		Total Market	
		Units	MS %	Units	MS %	Units	MS %	Units	%
DES	Q2 CY04	7,029	54%	6,046	46%			13,075	34%
	Q3 CY04	6,462	54%	5,417	46%			11,879	36%
	Q4 CY04	8,005	48%	8,303	50%	256	2%	16,564	43%
	Q1 CY05	9,558	47%	10,327	51%	429	2%	20,314	48%





NETHERLANDS

Netherlands		Cordis		Boston Scientific		Other		Total Market	
		Units	MS %	Units	MS %	Units	MS %	Units	%
DES	Q2 CY04	1,201	45%	1,440	55%			2,641	31%
	Q3 CY04	1,153	38%	1,844	62%			2,997	35%
	Q4 CY04	1,785	41%	2,566	59%	3		4,354	42%
	Q1 CY05	1,767	43%	2,328	57%	2		4,097	42%





BELGIUM

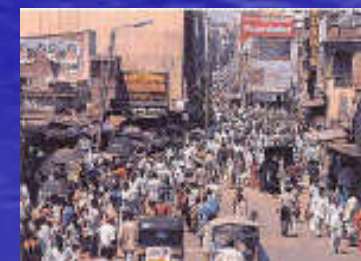
<i>Belgium</i>		Cordis		Boston Scientific		Other		Total Market	
		Units	MS %	Units	MS %	Units	MS %	Units	%
DES	Q2 CY04	883	41%	1,281	59%			2,164	26%
	Q3 CY04	914	46%	1,083	54%			1,997	27%
	Q4 CY04	1,042	43%	1,327	55%	55	2%	2,424	30%
	Q1 CY05	1,074	47%	1,162	51%	63	3%	2,298	29%





GERMANY

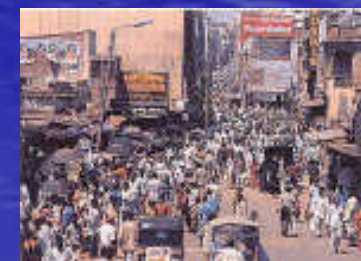
Germany		Cordis		Boston Scientific		Other		Total Market	
		Units	MS %	Units	MS %	Units	MS %	Units	%
DES	Q2 CY04	2,800	37%	4,735	63%			7,535	11%
	Q3 CY04	3,677	38%	5,986	62%			9,663	14%
	Q4 CY04	4,802	35%	8,812	64%	88	1%	13,702	18%
	Q1 CY05	4,941	34%	9,641	66%	123	1%	14,705	20%





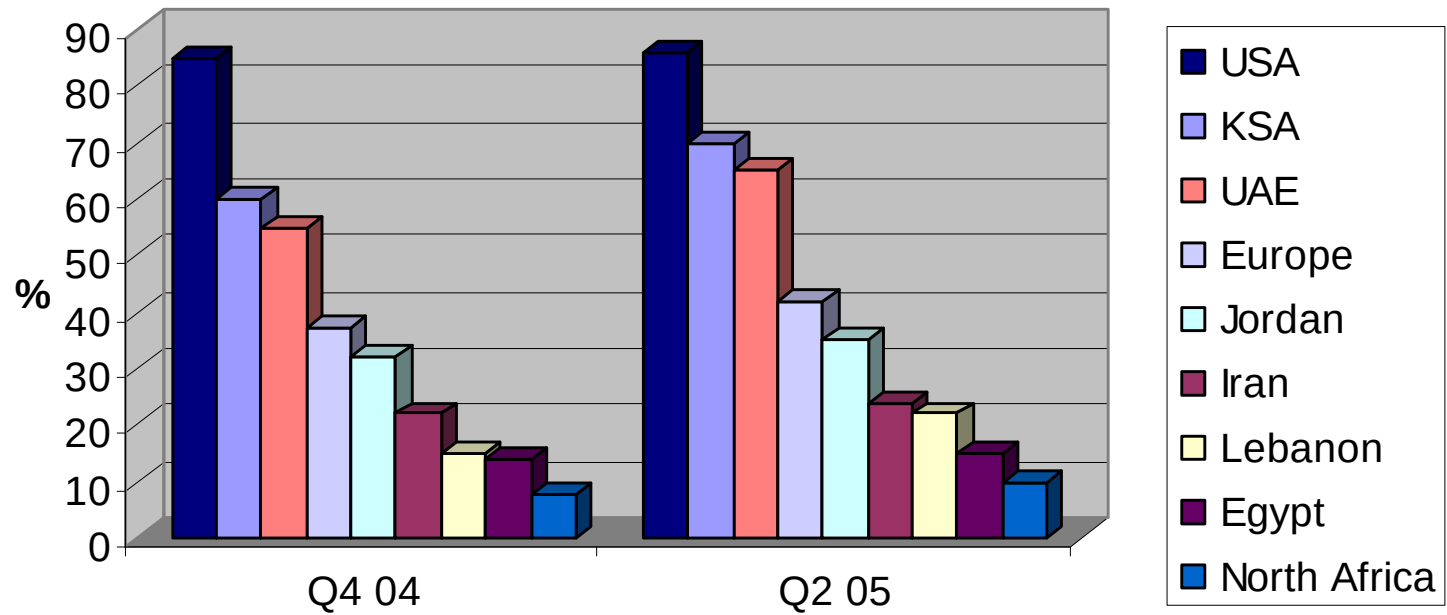
DES Penetration in USA

USA		Boston Scientific		Cordis		Total Market	
		Units	MS %	Units	MS %	Units	%
DES	Q2 CY04	19,863	68%	9,553	32%	29,416	79%
	Q3 CY04	17,834	60%	11,778	40%	29,612	84%
	Q4 CY04	18,932	63%	11,197	37%	30,129	85%
	Q1 CY05	18,403	60%	12,205	40%	30,608	86%





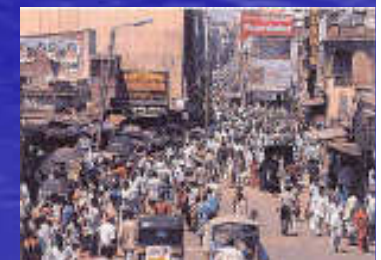
DES Penetration Rate Including USA & Europe





Conclusion

- **Interventional Cardiologists are increasingly treating more complex patients**
- **Efficacy and safety of The DES has been confirmed in most complex lesions and patient sub sets, including Diabetes, small vessels, instent restenosis, long lesions and chronic total occlusions**
- **DES can be cost effective by:**
 - ✓ Reducing **direct costs** of PCI or CABG for repeat revascularization
 - ✓ Reducing **indirect costs** including lost productivity, costs of additional cath lab capacity, and cost of delayed treatment
 - ✓ Providing an effective, safe PCI procedure with minimal risk of restenosis





**Unfortunately
the economic condition remains
the key player in expanding the
use of DES**



THE Real World
(DES 10%)



THE Real World
(DES 90%)

